

REMARKS

I. Status

Claims 1-45 are pending in the application. Withdrawn claims 40 and 43 are currently being cancelled. By the foregoing amendments, Applicants have amended claim 1 to define certain features of claim 14, which the Examiner indicates as being patentable over the presently cited citations. Claims 2-13, 15-39, 41-42, and 44-45 in their present form depend directly or indirectly from claim 1, or otherwise incorporate the patentable features of claim 14. In addition, Applicants are submitting new claims 46-86. Independent claim 46 defines certain features of claim 13, which the Examiner additionally indicates as being patentable over the presently cited citations. Claims 47-86 depend directly or indirectly from claim 46, or otherwise incorporate the patentable features of claim 13. Thus, all pending claims are believed to be allowable.

In addition, Applicants have amended the specification and certain claims to correct the spelling of the term "flavanolignan." Applicants also amended claim 1 to replace the alternative language "methyl amine and/or a flavanolignan" to require at least a flavanolignan and optionally a methyl amine. Further, Applicants are presenting certain clarifying amendments.

Claims 44 and 45 stand rejected under 35 U.S.C. § 112, ¶2. Claims 44 and 45 stand rejected under 35 U.S.C. § 101. Claims 8-9 and 35 stand rejected under 35 U.S.C. § 112, ¶2. Claims 1-2, 5-8, 11, 23-24, 29, 32-35, 37, 39, 41-42 and 44-45 stand rejected under 35 U.S.C. § 102(b) over US 5,397,786 ("Simone"). Claims 1, 5-8, 11-12, 17-24, 29, 32, and 41-42 stand rejected under 35 U.S.C. § 102(b) over WO 99/03365 ("Hageman"). Claims 3-4, 9-10, 12, 17, 19, 21, 30-31, 36 and 38 stand rejected under 35 U.S.C. § 103(a) over Simone. Claims 20 and 22 stand rejected under 35 U.S.C. § 103(a) over Simone in view of US 6,455,511 ("Kampinga"). Claims 25 and 28 stand

rejected under 35 U.S.C. § 103(a) over Simone in view of US 5,464,619 (“Kuznicki”). Applicants believe that all of the rejections are now overcome.

II. Allowable Subject Matter

Applicants thank the Examiner for indicating at page 9 of the present Office Action that claims 13-16 and 26 stand objected to as merely being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all features of the base claim and any intervening claims. Applicants have accordingly amended claim 1 by incorporating the features of original claim 14 as well as removing the “and/or” language of original claim 1. As such, claim 14 is cancelled by the foregoing amendments. Claims 2-45, which directly or indirectly depend from claim 1 or otherwise incorporate the patentable features of claim 1, are in condition for allowance at least by virtue of their dependency.

In addition, Applicants are presenting new claims 46-86. Independent claim 46 being similar to amended claim 1 incorporates the features of claim 13, which is allowable. Claims 47-86, which directly or indirectly depend from claim 46 or otherwise incorporate the features of claim 46, are in condition for allowance at least by virtue of their dependency.

Further, claim 26 as amended is now in independent form and incorporates the features of original claim 1 and intervening claim 23. Accordingly, claim 26 is now in condition for allowance.

No new matter is being presented by the foregoing amendments. Since all pending claims depend directly or indirectly from allowable claims 1 and 46 or otherwise incorporate the patentable features of claims 1 or 46, which define allowable subject matter, all pending claims are in condition for allowance and an indication to that effect is respectfully requested at this time.

III. Claims 44 and 45 Are Definite

Claims 44 and 45 stand rejected under 35 U.S.C. § 112, ¶2 as being indefinite for failing to recite positive method steps. While Applicants traverse this rejection, Applicants have amended claims 44 and 45 to recite methods of prevention and methods of treatment, respectively, using the fluids of claim 1.

Support for claims 44 and 45 is found at page 7, lines 4-10, where Applicants disclose:

A fluid according to the invention can be used for the treatment or prophylaxis of any type of dehydration in healthy or ill subjects, including water loss due to excessive sweating (heavy labor, sports, prolonged exposure to a hot environment, e.g. a humid hot environment), water loss due to diarrhea or due to the effects of diuretic drugs or too low water consumption (e.g. during long-distance traveling, elderly, hospital patients who stay long in bed and are staying in a warm environment, patients in a coma).

and at page 15, lines 15-19:

The invention also relates to a method for the prevention or treatment of dehydration of subjects who are exposed to high temperatures, and/or physical exercise, including labor and sport by administration of a fluid according to the invention to a subject before, during or after being exposed to said circumstance.

While not expressly cited by the Examiner, it is worth noting that claims 85 and 86 similarly recite methods of prevention and methods of treatment, respectively, using the fluids of claim 46.

Accordingly, Applicants respectfully request reconsideration of the amended claims and removal of the present rejection.

IV. Claims 44 and 45 Have Utility

Claims 44 and 45 stand rejected over 35 U.S.C. § 101 as lacking utility. Applicants respectfully traverse this rejection as to amended claims 44 and 45, which describe method inventions having utility. While not expressly cited by the Examiner, it is worth noting that claims

85 and 86 similarly describe method inventions having utility. Accordingly, Applicants respectfully request reconsideration of the amended claims and removal of the present rejection.

V. Claims 8-9 and 35 Are Definite

Claims 8-9 and 35 stand rejected under 35 U.S.C. § 112, ¶2 as being indefinite as to certain claim language. Applicants respectfully traverse this rejection.

The Examiner asserts that claim 8 is unclear because of the use of the phrase “one or more carbohydrates.” In response, Applicants have amended claim 8 to recite a single Markush group. While not expressly stated by the Examiner at page 3 of the Office Action, it is believed that claim 9 is rejected as merely being dependent from rejected claim 8 since the Examiner makes no specific comments regarding claim 9. Since claim 8 is now believed to be patentable, claim 9 is also deemed to be patentable.

While not expressly cited by the Examiner, it is worth noting that the text of claims 53 and 54 is similar to claims 8 and 9, as amended. Accordingly, claims 53 and 54 are also believed to be patentable for similar reasons.

The Examiner asserts that claim 35 is indefinite because it is allegedly not clear what types of diseases or conditions are referred to as “a physiologically or symptomatically related disorder.” While Applicants respectfully traverse this rejection, Applicants have deleted the phrase objected to by the Examiner.

While not expressly cited by the Examiner, it is worth noting that the text of claim 78 is similar to claim 35, as amended. Accordingly, claim 78 is also believed to be patentable for similar reasons.

Accordingly, Applicants respectfully request consideration and allowance of claims 8-9 and 35.

VI. Claims 1-2, 5-8, 11, 23-24, 29, 32-35, 37, 39, 41-42 and 44-45 Are Patentable Over Simone

Claims 1-2, 5-8, 11, 23-24, 29, 32-35, 37, 39, 41-42 and 44-45 stand rejected under 35 U.S.C. § 102(b) over Simone. Applicants respectfully traverse this rejection.

Claim 1 as amended defines a fluid for preventing or treating hypohydration, comprising a flavanolignan and optionally a methyl amine, said fluid further comprising one or more digestible carbohydrates and one or more minerals, wherein said fluid has an essentially hypotonic osmolarity, and wherein said flavanolignan is present at a concentration of 0.1-8 g/l. As indicated above, claim 1 as amended defines certain features of claim 14, notably flavanolignan being present at a concentration of 0.1-8 g/l, which the Examiner indicates at page 9 of the Office Action is allowable. Since the remainder of the cited claims depends directly or indirectly from claim 1, all cited claims are deemed to be patentable over the present citation at least by virtue of their dependency. Accordingly, removal of the present rejection is respectfully requested at this time.

Similarly, claim 46 defines a fluid for preventing or treating hypohydration, comprising a flavanolignan and optionally a methyl amine, said fluid further comprising one or more digestible carbohydrates and one or more minerals, wherein said fluid has an essentially hypotonic osmolarity, and wherein said flavanolignan is silibin. While not expressly cited by the Examiner, it is worth noting that claim 46 as amended defines certain features of claim 13, notably the flavanolignan being silibin, which the Examiner indicates at page 9 of the Office Action is allowable. Accordingly, all claims depending directly or indirectly from claim 46 are deemed to be patentable over the present citation at least by virtue of their dependency.

VII. Claims 1, 5-8, 11-12, 17-24, 29, 32, and 41-42 Are Patentable Over Hageman

Claims 1, 5-8, 11-12, 17-24, 29, 32, and 41-42 stand rejected under 35 U.S.C. § 102(b) over Hageman. Applicants respectfully traverse this rejection.

As indicated above, claim 1 as amended defines certain features of claim 14, notably flavanolignan being present at a concentration of 0.1-8 g/l, which the Examiner indicates at page 9 of the Office Action is allowable. Since the remainder of the cited claims depends directly or indirectly from claim 1, all cited claims are deemed to be patentable over the present citation. Accordingly, removal of the present rejection is respectfully requested at this time.

While not expressly cited by the Examiner, it is worth noting that claim 46 as amended defines certain features of claim 13, notably the flavanolignan being silibin, which the Examiner indicates at page 9 of the Office Action is allowable. Accordingly, all claims depending directly or indirectly from claim 46 are deemed to be patentable over the present citation as well.

VIII. Claims 3-4, 9-10, 12, 17, 19, 21, 30-31, 36 and 38 Are Patentable Over Simone

Claims 3-4, 9-10, 12, 17, 19, 21, 30-31, 36 and 38 stand rejected under 35 U.S.C. § 103(a) over Simone. Applicants respectfully traverse this rejection.

As indicated above, claim 1 as amended defines certain features of claim 14, notably flavanolignan being present at a concentration of 0.1-8 g/l, which the Examiner indicates at page 9 of the Office Action is allowable. Since the cited claims depend directly or indirectly from claim 1, all cited claims are deemed to be patentable over the present combination of citations. Accordingly, removal of the present rejection is respectfully requested at this time.

While not expressly cited by the Examiner, it is worth noting that claim 46 as amended defines certain features of claim 13, notably the flavanolignan being silibin, which the Examiner

indicates at page 9 of the Office Action is allowable. Accordingly, all claims depending directly or indirectly from claim 46 are deemed to be patentable over the present combination of citations as well.

IX. Claims 20 and 22 Are Patentable Over Simone in view of Kampinga

Claims 20 and 22 stand rejected under 35 U.S.C. § 103(a) over Simone in view of Kampinga. Applicants respectfully traverse this rejection.

As indicated above, claim 1 as amended defines certain features of claim 14, notably flavanolignan being present at a concentration of 0.1-8 g/l, which the Examiner indicates at page 9 of the Office Action is allowable. Since claims 20 and 22 depend directly or indirectly from claim 1, claims 20 and 22 are deemed to be patentable over the present combination of citations. Accordingly, removal of the present rejection is respectfully requested at this time.

While not expressly cited by the Examiner, it is worth noting that claim 46 as amended defines certain features of claim 13, notably the flavanolignan being silibin, which the Examiner indicates at page 9 of the Office Action is allowable. Accordingly, all claims depending directly or indirectly from claim 46 are deemed to be patentable over the present combination of citations as well.

X. Claims 25 and 28 Are Patentable Over Simone in view of Kuznicki

Claims 25 and 28 stand rejected under 35 U.S.C. § 103(a) over Simone in view of Kuznicki. Applicants respectfully traverse this rejection.

As indicated above, claim 1 as amended defines certain features of claim 14, notably flavanolignan being present at a concentration of 0.1-8 g/l, which the Examiner indicates at page 9 of

the Office Action is allowable. Since claims 25 and 28 depend directly or indirectly from claim 1, claims 25 and 28 are deemed to be patentable over the present combination of citations. Accordingly, removal of the present rejection is respectfully requested at this time.

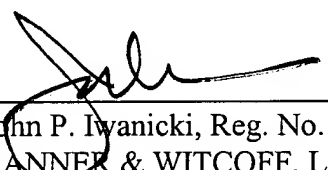
While not expressly cited by the Examiner, it is worth noting that claim 46 as amended defines certain features of claim 13, notably the flavanolignan being silibin, which the Examiner indicates at page 9 of the Office Action is allowable. Accordingly, all claims depending directly or indirectly from claim 46 are deemed to be patentable over the present combination of citations as well.

XI. Conclusion

Having addressed all outstanding issues, Applicants respectfully request removal of all rejections and allowance of all claims at this time. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

Dated: October 29, 2003



John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
Telephone: (617) 720-9600